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David T. Read
Acting Director Health Assessment Policy Staff, CDER
Food and Drug Administration
1451 Rockville Pike, HFD-7
Rockville, MD 20852

DEC 8 2003

Dear Mr. Read:

Transmitted herewith is a copy of the application for patent term extension of U.S. Patent No. 5,070,080. The application was filed on May 14, 2003, under 35 U.S.C. § 156.

The patent claims a method of use of a product that was subject to regulatory review under the Federal Food, Drug and Cosmetic Act. Subject to final review, the subject patent is considered to be eligible for patent term restoration. Thus, a determination by your office of the applicable regulatory review period is necessary. Since an application for patent term extension was also filed for U.S. Patent No. 4,937,234 based upon the same regulatory review period, the determination should reference both patents. The determination of the regulatory review period should reference Accordingly, notice and a copy of the application are provided pursuant to 35 U.S.C. § 156(d)(2)(A).

Inquiries regarding this communication should be directed to the undersigned at (703) 306-3159 (telephone) or (703)872-9411 (facsimile).

Karin Ferriter
Senior Legal Advisor
Office of Patent Legal Administration
Office of the Deputy Commissioner
for Patent Examination Policy

cc: Grace J. Fishel
11970 Borman Drive, Suite 220
St. Louis, MO 63146

RE: Neutersol (zinc gluconate)
Docket No. 03E-0405, 03E-0452